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\* Admitted in TX only  
\*\* Admitted in CT only

*Jfw*

August 2, 2005

MS Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Re: U.S. Patent Application No.: 10/822,235  
For: *COCHLEATE COMPOSITIONS DIRECTED AGAINST EXPRESSION OF  
PROTEINS*  
Inventors: Susan Gould-Fogerite, *et al.*  
Filed: April 9, 2004  
Our Ref. No.: BSZ-049

Dear Sir:

I enclose herewith for filing in the above-identified application the following:

1. Information Disclosure Statement;
2. PTO Form SB/08;
3. Copies of the selected references cited in PTO Form SB/08 (A27-D4);
4. A Return Postcard.

No additional costs are believed to be due in connection with the filing of this Information Disclosure Statement. However, please charge any necessary fees in connection with the enclosed statement to our Deposit Order Account No. 12-0080. For this purpose, a duplicate of this sheet is attached.

I hereby certify that this correspondence is deposited with the United States Postal Service as first class mail in an envelope addressed to: MS Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450 on:

August 2, 2005

Date

*[Signature]*  
Danielle L. Herritt, Registration No. 43,670

Respectfully submitted,  
LAHIVE & COCKFIELD, LLP

*[Signature]*  
Danielle L. Herritt  
Registration No. 43,670  
Attorney for Applicants



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of: Susan Gould-Fogerite, *et al.*

Serial No.: 10/822,235

Filed: April 9, 2004

For: *COCHLEATE COMPOSITIONS DIRECTED  
AGAINST EXPRESSION OF PROTEINS*

Attorney Docket No.: BSZ-049

Group Art Unit: 1653

Examiner: Not Yet Assigned

MS Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

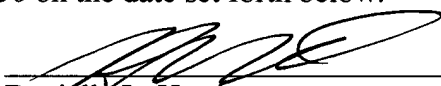
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August 2, 2005

Date of Signature and of Mail Deposit

By:

  
Danielle L. Herritt  
Registration No. 43,670  
Attorney for Applicants

INFORMATION DISCLOSURE STATEMENT

Dear Sir:

Applicants and their Attorney are aware of the following publications and information, listed on the attached PTO Form SB/08, and in accordance with 37 CFR §1.97 hereby submit these publications for the Examiner's consideration. A copy of each cited publication is enclosed. Copies of cited U.S. patents and U.S. publications (Reference ID Nos. A1-A26) are not enclosed with this statement. Copies of foreign patent documents and non-patent literature (Reference ID Nos. A27-D5) are enclosed in accordance with 37 CFR § 1.98.

Documents B4, B5, B8, B9, C4, C5, C9, C17 and C22, of the attached SB/08 were cited in an International Search Report and Written Opinion, issued January 27, 2005, during the prosecution of international application no. PCT/US2004/011020, which corresponds to the above referenced application. A copy of the International Search Report, Written Opinion and of each document required under 37 CFR 1.98(a)(2) cited thereon are enclosed as well. It is submitted that the Information Disclosure Statement is in compliance with 37 CFR 1.98 and the Examiner is respectfully requested to consider the listed references.

In addition, Applicant directs the Examiner's attention to the following United States patent applications.

U.S. Ser. No. (Attny. Docket #)	Filing Date
11/042,598 (BSZ-008DVCN)	01/24/05
11/040,615 (BSZ-009CPCN2)	01/18/05
10/304,567 (BSZ-010CN)	11/26/02
10/701,364 (BSZ-014)	11/03/03
10/759,381 (BSZ-017)	01/15/04
11/051,562 (BSZ-038)	02/03/05
11/047,373 (BSZ-039)	01/28/05
10/822,230 (BSZ-050)	04/09/04

This statement is not to be interpreted as a representation that the cited publications are material, that an exhaustive search has been conducted, or that no other relevant information exists. Nor shall the citation of any publication herein be construed *per se* as a representation that such publication is prior art. Moreover, Applicants understand that the Examiner will make an independent evaluation of the cited publications.

Under 37 CFR § 1.97(b)(3), no additional costs are believed to be due in connection with the filing of this disclosure. If, however, a first Office Action on the merits issues in this application bearing a mailing date prior to the date of this Information Disclosure Statement, please charge the appropriate fee as required under 37 CFR §1.17(p) to our Deposit Order Account No. 12-0080.

Respectfully submitted,  
LAHIVE & COCKFIELD, LLP

A handwritten signature in black ink, appearing to read 'DLH', is written over a horizontal line.

Danielle L. Herritt  
Registration No. 43,670  
Attorney for Applicants

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Date: August 2, 2005

DLH/EAH/BCT/rl  
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<b>Substitute for form 1449A/B/PTO</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	10/822,235
				Filing Date	April 9, 2004
				First Named Inventor	Susan Gould-Fogerite
				Art Unit	1653
				Examiner Name	Not Yet Assigned
Sheet	1	of	4	Attorney Docket Number	BSZ-049

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
	A1	4,078,052	03-07-1978	Papahadjopoulos	
	A2	4,725,442	02-16-1988	Haynes	
	A3	4,871,488	10-03-1989	Mannino, <i>et al.</i>	
	A4	4,874,795	10-17-1989	Yesair	
	A5	4,906,476	03-06-1990	Radhakrishnan	
	A6	4,990,291	02-05-1991	Schoen, <i>et al.</i>	
	A7	5,026,557	06-25-1991	Estis, <i>et al.</i>	
	A8	5,100,591	03-31-1992	Leclef, <i>et al.</i>	
	A9	5,269,979	12-14-1993	Fountain	
	A10	5,409,698	04-25-1995	Anderson, <i>et al.</i>	
	A11	5,571,517	11-05-1996	Yesair	
	A12	5,580,859	12-03-1996	Feigner, <i>et al.</i>	
	A13	5,589,466	12-31-1996	Feigner, <i>et al.</i>	
	A14	5,643,574	07-01-1997	Gould-Fogerite, <i>et al.</i>	
	A15	5,834,015	11-10-1998	Oleske, <i>et al.</i>	
	A16	5,840,707	11-24-1998	Mannino, <i>et al.</i>	
	A17	5,994,318	11-30-1999	Gould-Fogerite, <i>et al.</i>	
	A18	6,120,751	11-19-2000	Unger	
	A19	6,153,217	11-28-2000	Jin, <i>et al.</i>	
	A20	6,340,591	01-22-2002	Margolis, <i>et al.</i>	
	A21	6,403,056	06-11-2002	Unger	
	A22	6,406,713	06-18-2002	Janoff, <i>et al.</i>	
	A23	6,447,800	09-10-2002	Hope	
	A24	6,592,894	07-15-2003	Zarif, <i>et al.</i>	
	A25	2004/0092727	05-13-2004	Jin	
	A26	6,808,720	10-26-2004	Unger	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)				
	A27	FR 2221122 A	10-11-1974	Bayer AG		Abat
	A28	WO 96/025942 A1	08-29-1996	Albany Medical College, <i>et al.</i>		

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature		Date Considered	
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Substitute for form 1449A/B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	10/822,235
				Filing Date	April 9, 2004
				First Named Inventor	Susan Gould-Fogerite
				Art Unit	1653
				Examiner Name	Not Yet Assigned
Sheet	2	of	4	Attorney Docket Number	BSZ-049

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Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)	MM-DD-YYYY			
	B1	WO 97/030725 A1	08-28-1997	Mannino, <i>et al.</i>		
	B2	WO 00/042989 A2,A3	07-27-2000	Biodelivery Sciences Inc., <i>et al.</i>		
	B3	WO 01/052817 A2,A3	07-26-2001	Biodelivery Sciences Inc., <i>et al.</i>		
	B4	WO 02/044321 A2,A3	06-06-2002	Max Planck Gesellschaft		
	B5	WO 02/097114 A2	12-05-2002	Ribozyme Pharmaceuticals, Inc.		
	B6	WO 04/012709 A1	02-12-2004	Jin		

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NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	B7	Anderson, <i>et al.</i> "Formulation and evaluation of a folic acid receptor-targeted oral vancomycin liposomal dosage form." <i>Pharm Res.</i> 2001; 18(3):316-22.	
	B8	Brummelkamp, <i>et al.</i> "A system for stable expression of short interfering RNAs in mammalian cells." <i>Science.</i> 2002 Apr 19; 296(5567):550-3.	
	B9	Burghoorn, <i>et al.</i> "Molecular evaluation of the plasma membrane proton pump from <i>Aspergillus fumigatus</i> ." <i>Antimicrob Agents Chemother.</i> 2002 Mar; 46(3):615-24.	
	B10	Couvreux, <i>et al.</i> "Nano- and microparticles for the delivery of polypeptides and proteins." <i>Adv. Drug Delivery Rev.</i> 1993; 10:141-62.	
	B11	Gould-Fogerite, <i>et al.</i> "Chimerasome-mediated gene transfer in vitro and in vivo." <i>Gene.</i> 1989; 84(2):429-38.	
	B12	Gould-Fogerite, <i>et al.</i> "Rotary dialysis: its application to the preparation of large liposomes and large proteoliposomes (protein-lipid vesicles) with high encapsulation efficiency and efficient reconstitution of membrane proteins." <i>Anal Biochem.</i> 1985; 148(1):15-25.	
	B13	Gould-Fogerite, <i>et al.</i> "The reconstitution of biologically active glycoproteins into large liposomes: use as a delivery vehicle to animal cells." <i>Adv Memb Biochem Bioener.</i> 1988; 569-86.	
	B14	Gould-Fogerite, <i>et al.</i> "Liposome preparation and related techniques." <i>Liposome Technology.</i> 2 <sup>nd</sup> Edition. 1993; 1:67-80.	
	B15	Gould-Fogerite, <i>et al.</i> "Interaction of liposomes with the biological milieu." <i>Liposome Technology.</i> 2 <sup>nd</sup> Edition. 1993; 3:261-76.	
	B16	Gould-Fogerite, <i>et al.</i> "Mucosal and systemic immunization using cochleate and liposome vaccines." <i>J. Liposome Res.</i> 1996; 6(2):357-79.	

Examiner Signature		Date Considered	
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	C1	Gould-Fogerite, <i>et al.</i> "Targeting immune response induction with cochleate and liposome-based vaccines." <i>Adv Drug Delivery Rev.</i> 1998; 32(3):273-87.		
	C2	Gould-Fogerite, <i>et al.</i> "Cochleates for induction of mucosal and systemic immune responses." <i>Meth Molec Med.</i> 1999; 42:179-96.		
	C3	Gould-Fogerite, <i>et al.</i> "Cochleate Delivery Vehicles: Applications in Vaccine Delivery." <i>J Liposome Res.</i> 2000; 10(4):339-58.		
	C4	Gould-Fogerite, <i>et al.</i> "Cochleate Delivery Vehicles: Applications to Gene Therapy." 2003 Mar/Apr; 3(2):41-7.		
	C5	Hu, <i>et al.</i> "ERB-B-2/NEU DNA vaccine based immunotherapy." <i>International Congress of Immunology Abstracts.</i> Budapest, Hungary. 1995 Jul 23; 870.		
	C6	Lavelle, <i>et al.</i> "Improved methods for the delivery of liposome-sequestered RNA into eucaryotic cells." <i>Arch Biochem Biophys.</i> 1982; 215(2):486-97.		
	C7	Lichtenberg, <i>et al.</i> "Liposomes: Preparation, characterization and preservation." <i>Meth Biochem Anal.</i> 1988; 33:337-462.		
	C8	Longenecker, <i>et al.</i> "Three dimensional structure of mammalian casein kinase I: Molecular basis for phosphate recognition." <i>J Mol Biol.</i> 1996; 257:618-31.		
	C9	Lu, <i>et al.</i> "siRNA-mediated antitumorigenesis for drug target validation and therapeutics." <i>Curr Opin Mol Ther.</i> 2003 Jun; 5(3):225-34.		
	C10	Mannino, <i>et al.</i> "Liposome mediated gene transfer." <i>Biotechniques.</i> 1988; 6(7):682-90.		
	C11	Mannino, <i>et al.</i> "Liposomes as adjuvants for peptides: Preparation and use of immunogenic peptide-phospholipid complexes." <i>Liposome Technology.</i> 2 <sup>nd</sup> Edition, 1993; 2:167-84.		
	C12	Mannino, <i>et al.</i> "Lipid matrix-based vaccines for mucosal and systemic immunization." <i>Pharm Biotechnol.</i> 1995; 6:363-87.		
	C13	Mannino, <i>et al.</i> "Antigen cochleate preparations for oral and systemic vaccinations." <i>New Gen Vaccines.</i> 2 <sup>nd</sup> Edition, 1997; Ch 18, 229-39.		
	C14	Papahadjopolous, <i>et al.</i> "Cochleate lipid cylinders: Formation by fusion of unilamellar vesicles." <i>Biochim Biophys Acta.</i> 1975; 394(3):483-91.		
	C15	Papahadjopolous, <i>et al.</i> "The use of lipid vesicles for introducing macromolecules into cells." <i>Prot Turnover Lysosome Funct.</i> 1978; 543-60.		
	C16	Parker, <i>et al.</i> "In vivo and in vitro antiproliferative effects of antisense interleukin 10 oligonucleotides." <i>Meth Enzym: Antisense Tech, Part B.</i> 1999; 314:411-29.		
	C17	Paroo, <i>et al.</i> "Challenges for RNAi in vivo." <i>Trends Biotechnol.</i> 2004 Aug; 22(8):390-4.		
	C18	Sanderson, <i>et al.</i> "Encapsulation of vancomycin and gentamycin with cationic liposomes for inhibition of growth of <i>Staphylococcus epidermidis</i> ." <i>J Drug Target.</i> 1996; 4(3):181-9.		
	C19	Santangelo, <i>et al.</i> "Efficacy of oral cochleate-amphotericin B in a mouse model of systemic candidiasis." <i>Antimicrob, Agents Chemother.</i> 2000; 2356-60.		
	C20	Sundram, <i>et al.</i> "General and efficient method for the solution- and solid-phase synthesis of vancomycin carboxamide derivatives." <i>J Org Chem.</i> 1995; 60:1102-3.		
	C21	Wassef, <i>et al.</i> "Liposomes as carriers for vaccines." <i>Immunomethods.</i> 1994; 4(3):217-22.		
	C22	Yamamoto, <i>et al.</i> "Human C-ERB-B-2 MRNA." <i>Genbank.</i> 1995 Mar 30; XP002264793.		

Examiner Signature		Date Considered	
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	D1	Zarif, <i>et al.</i> "Amphotericin B cochleates as a novel oral delivery system for the treatment of fungal infection." <i>Proceedings of the International Symposium on Controlled Release of Bioactive Materials</i> . Illinois: Controlled Release Society, 1999; 964-5.	
	D2	Zarif, <i>et al.</i> "Antifungal activity of amphotericin B cochleates against <i>Candida albicans</i> infection in a mouse model." <i>Antimicrob. Agents Chemother.</i> 2000; 1463-9.	
	D3	Zarif, <i>et al.</i> "Cochleates: New lipid based drug delivery system." <i>J. Liposome Res.</i> 2000; 10(4):523-38.	
	D4	Zarif, <i>et al.</i> "Elongated supramolecular assemblies in drug delivery." <i>J. Controlled Rel.</i> 2002; 81:7-23.	
	D5	International Search Report and Written Opinion for Application No. PCT/US2004/011020	

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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